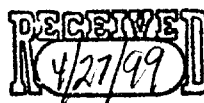




B.F. ASCHER & COMPANY, INC. • *Pharmaceuticals • Consumer Products*

304 '99 MAY 7 12:13

April 21, 1999



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

RE: Notification Submitted Pursuant to DSHEA Section 6

Dear Madam/Sir:

B. F. Ascher & Company, Inc. submits this letter to satisfy the notification requirements established by Section 6 of the Dietary Supplement Health and Education Act of 1994 ("DSHEA") and 21 C.F.R. § 101.93 for its product Melagesic™ PM. The information in this notification is presented in the order set forth in 21 C.F.R. § 101.93.

1. **101.93(a)(2)(i) - the name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement**

The distributor of the dietary supplement is:

B. F. Ascher & Company, Inc.
15501 West 109th Street
Lenexa, Kansas 66219

2. **101.93(a)(2)(ii) - the text of the statement that is being made**

As permitted by Section 6 of the DSHEA, the Melagesic™ PM dietary supplement will bear the following, or substantially similar, claims:

- "Melatonin to help enhance natural, restful sleep"
- "Promotes natural, restful sleep"
- "...nature's own sleep enhancer, melatonin."
- "...helps you promote natural, restful sleep."

3. **101.93(a)(2)(iii) - the name of the dietary ingredient or supplement that is the subject of the statement**

Melatonin

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4. 101.93(a)(2)(iv) - the name of the dietary supplement on whose label, or in whose labeling, the statement appears

The supplement is marketed under the trade name "Melagesic™ PM."

On behalf of B. F. Ascher, I certify that the information presented in this notification is complete and accurate. Further, B. F. Ascher possesses substantiation that the statements identified in Paragraph 2 are truthful and not misleading.

If you have any questions concerning this notification, please contact me.

Sincerely,



Charles H. Borchers
Vice President - Scientific
& Legal Affairs

CHB:djc

Certified Mail/
Return Receipt Requested